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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/284,107	10/25/99	LOGTENBERG T	313632000600

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KATE H MURASHIGE
MORRISON & FOERSTER
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO CA 92130-2332

EXAMINER	
BHATTI, T	
ART UNIT	PAPER NUMBER
1627	18

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application N .	Applicant(s)	
	09/284,107	LOGTENBERG ET AL.	
	Examin r	Art Unit	
	Tahira H Bhatti	1627	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) 2,4,11 and 12 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) 1,3 and 5-10 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

Status of the Claims

Claims 1-12 are currently pending.
Claims 2,4 and 11-12 are withdrawn from consideration as being directed to a nonelected invention.
Claims 1,3 and 5-10 are under consideration.

Election/Restriction

Applicant's election with traverse of Group I (claims 1,3 and 5-10 in Paper No.1 on 8/16/01) is acknowledged. The traversal with regard to restriction is that "the examiner has not met his/her burden that the restricted claims are drawn to independent or distinct invention". This is not found persuasive for all the reasons put forth by the Examiner and none of which were rebutted by applicant. Hence the requirement is proper and is therefore made FINAL.

Claims 2,4 and 11-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1 (and dependent claims) the term (s) "specific binding and comprising" as defined in multiple instances in the specification page 1 are relative terms, which render the claim indefinite. The term "specific binding derivatives or fragments" is not defined by the claims and the specification does not provide a standard for

ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

B. Claim 3 (and dependent claims) is rejected since there is no metes and bounds regarding which peptides capable of binding and peptides not capable of binding , nor the relative information of synthesizing oligopeptides derived from the proteinaceous target within the scope of the presently claimed invention is provided.

C. In claims 7 (and dependent claims), the term "encoding sequencing " lacks metes and bounds regarding the encompassed constituents and the ultimate structure.

D. Regarding claim 9, the phrase "preferably" renders the claim indefinite because it is not clear what the "preferable" features are, nor what else the claimed single chain peptide might comprise. See MPEP § 2173.05.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3 and 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for proteinaceous targets as described in

specification page 1, does not reasonably provide enablement for the full scope of of these fixated biological molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered in a determination of undue experimentation are disclosed in In re Wands (USPQ 2d 1400: CAFC 1988) which include:

a. The breadth of the claims. b. The nature of the invention. c.The state of the prior art. d. The level of one of ordinary skill. e. The level of predictability in the art. f. The amount of direction provided by the inventor. g. The presence or absence of working examples h. The quantity of experimentation necessary needed to make or use the invention based on the disclosure. See :In re Wands USPQ 2d 1400 (CAFC 1988).

The breadth of the claims

The breadth of potential for identifying a peptide capable of specifically binding to a proteinaceous target, of different chemical structure as encompassed by claims 1 and 3 (especially claim 1) is huge in light of the failure to specifically claim, the specific binding between the peptide and the target on a solid phase is a failure to specifically claim the metes and bounds regarding the chemical nature of the peptide and the fixated chemical target portions as well as sustituents therefrom for example as described in the indefinite rejection above:

A. In claim 1 (and dependent claims) the term (s) "specific binding , comprising and displaying" lacks metes and bounds as to the identification and resulting structure encompassed by the claimed invention.

B. In claims 1,3 and 5-10 (and dependent claims), the term "peptides on the surface of a replicable display package" lacks metes and bounds regarding the encompassed substituents and the identification.

The nature of the Invention/State of the Prior Art

The present invention as claimed is broadly directed to any method of identifying a peptide, comprising displaying the peptide on the surface of a display package and synthesizing oligopeptides "derived from" any proteinaceous target. Additionally, it is noted that the nature and placement of the proteinaceous target on the solid phase, plays a critical role in binding activity.

In this regard it is further noted, that critical or essential parameters to practice the invention, but not included in the claim(s), is not enabled by the disclosure. See In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976); Ex parte Bhide (BdPatApp&Int) 42 USPQ2d 14.

The amount of direction/working examples

The specification only provides guidance and examples directed to the method of making and use of replicable display package, and of displaying the peptide on the surface of said package. This does not provide enough guidance as to the specific antibody or a specific region or domain of the antibody which would selectively bind to

a proteinaceous target. This is not representative of the scope of claimed methods, to identifying specific molecules, derived from specific binding peptides or antibodies for affinity selection to bind to the target molecule.

Quantity of Experimentation

Due to the lack of representative examples regarding the method of identification, and binding specificity of a representative sample of peptide the amount of experimentation would be undue.

Accordingly, in light of the unpredictability surrounding the method of identifying peptides of diverse structure which possess a specific binding activity, the undue breadth of the claimed invention, the lack of adequate guidance, the lack of metes and bounds regarding claimed substituents, one wishing to practice the presently claimed invention would be unable to do so without engaging in undue experimentation. .

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-7, 10 is rejected under 35 U.S.A. 102(b) as being clearly anticipated by Ladner in viewof patent N0. W092,156,77

Ladner clearly shows that the genes encoding disulfide _bonded micro-proteins (i.e. peptides) expressed on the surfaces of bacterial cells, spores or phage. The resulting display phage library in his study includes BPT1 (58 residues) and Crambin (46) residues is screened for members having the ability to bind to a proteinaceous target of interest.

Claim 1 and 3 are rejected under 35 U.S.A. 102(b) as being clearly anticipated by Mehta et al. in view of U.S. Pat. No. W0 92/08738 or its U.S. equivalent example of Ishikawa; U.S. Pat. N0 52/36849.

The cited reference discloses a test sample containing Hepatitis C Virus (HCV) antigen, contacting with a solid phase to which a monoclonal or polycolonal anti-HCV antibody or a fragment has been bound. Here it is clearly understood that Mehta et. al. described a solid phase with specific proteins or antigens, for binding specific antibodies that are within the scope of the presently claimed (e.g. claims 1 and 3) inventions.

Claims 1, 3 and 5-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Catherine et al Pat N0. 58/44093,

There studies teach, single –chain Fvs genetic libraries (DNA, Phage) prepared from immunized mouse cells, to create antibody molecules with the mouse variable regions

joined to human constant regions. These single _chain Fvs agents are used for the diagnosis and therapy of human tumors.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3 are rejected under 35 U.S.C. 102 (b) and 35 U.S.C. 103(a) as being unpatentable over WO. Patent No. 95/15982 to Barsomian.

He teaches the use of a replicable genetic display package in an immunoreactive context which permits the antibody (e.g. peptide/protein) to bind to an antigen (protein) that is contacted with the display package, which embraces Applicants claimed inventions, see the entire document, especially lines 26-31 and 32-37 on page 2. Further more it discloses that the display library can be a phage and can be generated on a bacterial cell surface or a spore, see lines 1-3 page 3.

Instant claims are drawn to methods for identifying a peptide capable of specific binding to a proteinaceous target, comprising displaying the peptide on the

surface of a replicable display package, synthesizing oligopeptides derived from the proteinaceous target on a solid phase.

Instant claims differ from the reference in claiming, displaying the peptide on the surface of a replicable display package, and synthesizing oligopeptides derived from the proteinaceous target, The peptides and antibodies are randomly produced as large collection of different molecules, expressed on the surface of a replicable genetic package from where antibodies are affinity-selected for binding to the target molecule. where as prior art teaches that the antibody

variable regions are presented in the replicable genetic display package in an immunoreactive context which permits the antibody to bind to an antigen that is contacted with the package.

Thus, in prior art, affinity selection techniques are utilized to enrich the Population of display packages for those having antibody variable regions. Therefore, It would have been obvious to one having skill at the time the invention was made to further modify and obtain the phage display packages where single chain variable regions of antibody were inserted in phage genes and thus antibody fragment are affinity selected for binding to the molecule of interest. Hence phage display libraries have been obtained from prior art to modify antiibody-coat protein fusion and identification of specific peptides.

General inf rmation regarding further corresp ndence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Tahira Bhatti whose telephone number is (703) 605-1203.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsana Venkat (art unit 1627), can be reached at (703) 308 0570

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (702) 308-0196

Tahira Bhatti (art unit 1627)

October Nov. 5th, 2001

BENNETT CELSA
PRIMARY EXAMINER